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ORIGINAL ARTICLE

Impact of sphincter lesions and delayed sphincter repair on sacral neuromodulation treatment outcomes for faecal incontinence: results from a Finnish national cohort study

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Abstract

Purpose The aim of this multicentre study was to analyse the effects of patent sphincter lesions and previous sphincter repair on the results of sacral neuromodulation (SNM) treatment on patients with faecal incontinence (FI).

Methods Patients examined by endoanal ultrasound (EAUS) with FI as the indication for SNM treatment were included in the study. Data was collected from all the centres providing SNM treatment in Finland and analysed for differences in treatment outcomes.

Results A total of 237 patients treated for incontinence with SNM had been examined by EAUS. Of these patients, 33 had a history of previous delayed sphincter repair. A patent sphincter lesion was detected by EAUS in 128 patients. The EAUS finding did not influence the SNM test phase outcome ($p = 0.129$) or the final treatment outcome ($p = 0.233$). Patient's history of prior sphincter repair did not have a significant effect on the SNM test ($p = 0.425$) or final treatment outcome ($p = 0.442$).

Conclusions Results of our study indicate that a sphincter lesion or previous sphincter repair has no significant effect on the outcome of SNM treatment. Our data suggests that delayed sphincter repair prior to SNM treatment initiation for FI is not necessary.

Keywords Faecal incontinence · Sacral neuromodulation · Endoanal ultrasound · Obstetric anal sphincter injury · Anal sphincter repair

Introduction

Faecal incontinence (FI) has a serious negative effect on the quality of life, and it is estimated that 4–12% of the general population suffers from FI [1–3]. One of the main causes of FI in women is obstetric trauma. Obstetric trauma occurs in around 1–2% of all births and may present in the form of a perineal tear or nerve damage [4]. As many as 51% of women who have experienced an obstetric anal sphincter injury (OASI) present with FI in the long term [5]. Over half (71%) of the patients with a history of OASI have residual sphincter tears detected on later imaging studies [6–8]. At the beginning of this millennium, the gold standard for treatment of residual sphincter tears arising from OASI and other types of anal sphincter injuries was the overlapping sphincteroplasty [9, 10].

The results of delayed sphincter repair, sometimes performed years after initial trauma, have been disappointing, with only a few patients having satisfactory continence at long-term follow-up [11, 12]. This lack of positive effect is

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particularly evident in the elderly patient population [11]. Typically, physicians diagnosing patients with residual sphincter lesions by endoanal ultrasound (EAUS) or magnetic resonance tomography (MRT) have advocated a conservative approach as the first line of treatment, except when such patients present with a perineal defect or rectovaginal fistula [13]. Though most patients experience alleviation of symptoms with conservative treatment, there are patients who fail to respond. Even if conservative treatment is effective at first, symptoms of FI tend to re-emerge over time [10, 14, 15]. Symptoms of FI usually worsen after menopause due to weakening of the pelvic floor musculature [16].

Since its introduction in the 1990s, sacral neuromodulation (SNM) has established itself as the first line of treatment for FI unresponsive to conservative methods [13, 17].

There is data indicating that intact sphincters are not necessary to achieve successful SNM treatment results [18–20]. Studies on this matter have been conducted on small patient populations (26–63 patients) with no long-term results [20–22]. Contrary studies showing that intact sphincter musculature has a positive effect on SNM treatment outcome have also been published [23–25].

The aim of this study was to investigate the effect of different types of sphincter lesions detected on EAUS on SNM treatment results in a national cohort. The secondary aim was to compare the results of SNM treatment of patients with previous sphincter repair to patients with sphincter lesions and no previous sphincter repair prior to SNM treatment initiation.

Methods

This is a national register-based retrospective study performed in all centres providing SNM treatment in Finland. Clinical data of patients selected for SNM testing was collected from electronic patient register files from each of the participating institutions for further analysis. Patients who had undergone EAUS imaging, with FI as the primary or secondary indication for SNM treatment, were selected for further analysis.

Patients were divided into four groups according to the EAUS finding: patients with normal sphincter musculature, patients with an external anal sphincter (EAS) defect, patients with an internal anal sphincter (IAS) defect and patients with a combined IAS and EAS defect.

The groups were analysed for differences in age, sex, aetiology of FI, Wexner scores, anomanometry test results, number of attempted SNM tests, device settings during testing and rates of complications during testing and after permanent SNM implantation. Test phase and final treatment results were also compared between the groups. Patients with previous repair of the anal sphincter musculature were compared to patients without a history of anal sphincter repair for the same parameters mentioned above. Additionally, we compared the test phase and final treatment success rates between patients with a patent EAS defect and no previous sphincter repair to patients with a history of previous sphincter repair.

As Finnish centres do not have a standardised method for evaluating test phase or final treatment outcome, a universally applicable definition of treatment success was chosen. Test phase success was defined by patients advancing to permanent SNM implantation. Overall treatment success was defined by patients having a working permanent SNM device with subjective positive effects on the symptoms on FI at the time data collection ended on April 1, 2017.

The SNM implantation was performed as a two-stage procedure. Patients were first implanted with a test lead. This procedure was conducted under local anaesthesia, unless patient-dependent factors required otherwise. From 2002, all patients were implanted with a tined lead (see Appendix 2). All centres used a two-week evaluation period; the success of the test period was evaluated by either a drop in FI episodes according to a bowel diary or a drop in Wexner scores. All centres used subjective patient feedback as the main indication for permanent SNM implantation. All patients were evaluated 1, 6, and 12 months after the permanent modulator implantation. After one year of follow-up, patients were instructed to contact the incontinence nurse if any problems arouse with the SNM device. Subjective loss of effect in the presence of a working SNM was an indication for explantation of the SNM device.

Imaging data was collected from written imaging reports. The EAUS imaging devices were all supplied by BK Medical®. The models used varied over the period of 1999–2017 (for further information, see Appendix 1). All of the EAUS imaging studies were conducted by colorectal surgeons. All of the implanted devices were supplied by Medtronic® Inc. (Minneapolis, Minnesota, USA; see Appendix 2).

Microsoft® Excel® for MAC version 15.13.1 was used for data collection. IBM® SPSS® software Version 25 was used for statistical analysis. The Shapiro-Wilk test was performed to check for normality, where $p > 0.05$ indicated a normal distribution. None of the values expressed a normal distribution, so nonparametric tests were used. For continuous values, the Kruskal-Wallis independent samples test was used, where a p value of < 0.05 indicated a significant difference in means. When a significant difference was noted, the groups were further analysed with the Mann-Whitney U test to determine the differences between groups. The p values were corrected using Bonferroni's method. Either Pearson's chi-square test or the Fisher's exact test was used to compare nominal values. The overall change in pre- and post-testing Wexner scores was tested using the single sample t test. A p value of <0.05 was set as statistically significant.

This study was conducted in accordance with Finnish Medical Research Act 488/199, 295/2004 and approved by the Ethics Committee of the Hospital District of Southwest Finland (ETMK: 163/1801/2015).

Results

There were 237 patients examined by EAUS. One patient was excluded from further analysis because the indication for initiating SNM treatment was constipation (Fig. 1). Of the remaining 236 patients, 33 had a history of delayed sphincter repair. Of these, 31 patients had undergone an overlapping sphincteroplasty and two patients a graciloplasty procedure. Over half of the patients ($n = 17$; 51.5%) who had undergone delayed sphincter repair had a patent EAS defect detected on EAUS. In total, there were 128 patients with sphincter defects detected by EAUS. The majority of the patients were female ($n = 215$; 91.1%), and the median age of patients was 64.5 years. The most common indication for initiating SNM treatment was OASI ($n = 93$; 39.4%). Almost all of the patients who had undergone delayed sphincter repair had either a history of OASI ($n = 29$; 87.9%) or iatrogenic injury ($n = 3$; 9.1%) ($p < 0.001$). Only 18 (7.6%) of the test procedures were conducted under general anaesthesia. Of the 236 patients included in the study, 171 (73.1%) had a successful test phase and advanced to permanent SNM implantation; of these, 160 (60.6%) had a successful final treatment outcome. The median follow-up time from permanent SNM implantation was 1.3 years (range 14 days–13.6 years).

Effects of different types of sphincter lesions on the SNM treatment outcome

As patients were divided into four subgroups according to the EAUS finding, there was no significant difference in the age of patients between the groups ($p = 0.558$). Significantly more women had an EAS or a combined EAS and IAS defect compared to male patients ($p = 0.008$).

No significant differences between the groups in the squeeze ($p = 0.182$) or resting pressures ($p = 0.254$) were shown in the anomanometric study (Table 1). All of the patients' pre-testing and during-testing Wexner scores changed significantly, with scores dropping from a mean of 15.7 to 8.81 ($p < 0.001$), with only 28 (11.8%) patients having filled out the Wexner questionnaire after test initiation. There was no difference between the groups in the mean Wexner scores prior to testing ($p = 0.439$) or in the values obtained during testing ($p = 0.279$; see Table 2). An average of 1.13 (SD) tests were performed per patient, with 26 patients undergoing testing more than once, with no differences between groups ($p = 0.409$).

The test phase and permanent SNM settings are presented in Table 3. There was no difference in complication frequencies between patients in different groups ($p = 0.194$). Infection ($n = 15$) and postoperative pain ($n = 11$) were the most common complications arising during SNM testing.

Patients with a combined EAS and IAS defect had most successful test phases, with 84.0% of these patients advancing from the test phase to permanent SNM implantation. Patients with an EAS defect had the least successful test phases, with 64.0% of the patients advancing to permanent SNM

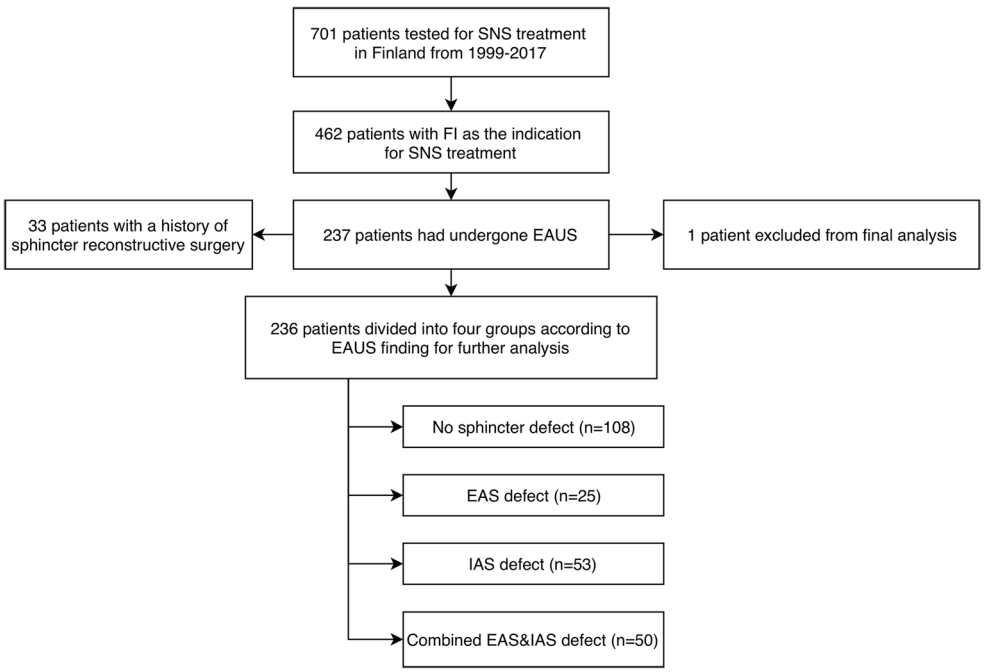

Fig. 1 Flowchart showing the selection of patients

Table 1 Anomanometry results of patients ($n = 90$; 38.1%) with different types of sphincter lesions

	Squeeze pressure (median)	Resting pressure (median)
Normal sphincters	72	37.35
Pathologic EAS	44.15	31
Pathologic IAS	83	38.4
Pathologic EAS and IAS	46.5	23
p value[1]	0.360	0.607
Sphincter repair	48	30
No sphincter repair	65.3	36
p value[2]	0.933	0.859

[1] Kruskal-Wallis test, [2] Mann-Whitney U test

EAS external anal sphincter, *IAS* internal anal sphincter

implantation. Of the patients with normal sphincter musculature, 73.8% had a successful test phase outcome. These differences were not significant ($p = 0.129$). Neither was there a significant difference between the groups in the final treatment outcome ($p = 0.233$).

Effect of delayed sphincter repair on SNM treatment outcomes

Altogether, 33 (14.9%) of the patients included in the study had a history of previous delayed sphincter repair. Two patients had undergone a graciloplasty procedure, whereas the rest of the patients had undergone an overlapping sphincteroplasty. Only one male patient had undergone sphincter repair, which was due to iatrogenic sphincter injury.

There was no difference between patients with previous delayed sphincter repair and patients with no history of repair in the anomanometry study results (Table 1).

Table 2 Median Wexner scores prior testing and during the test phase

	Median Wexner score before testing	Median Wexner scores during testing
Normal sphincters	15	7
Pathologic EAS	15.5	10
Pathologic IAS	17	14
Pathologic EAS and IAS	16	6
p value	0.439	0.163
Number of patients analysed	192	73
Sphincter repair	16	15
No sphincter repair	16	6.5
p value	0.696	0.789
Number of patients analysed	190	72

p values obtained using the single sample t test

EAS external anal sphincter, *IAS* internal anal sphincter

There were proportionally more patients with a history of delayed sphincter repair ($n = 9$, 28.1%) who had been tested for SNM implantation more than once compared to patients with no history of sphincter reconstructive surgery ($n = 17$, 8.5%) ($p = 0.005$). Patients with previous sphincter reconstructive surgery had longer signal length settings during testing compared to patients with no history of surgical sphincter reconstructive surgery ($p = 0.016$). Otherwise, no differences in the test phase signal settings were detected.

A history of prior sphincter reconstructive surgery did not have a significant effect on the test results, as 26 (78.8%) of the patients with prior sphincter reconstructive surgery and 145 (72.1%) of the patients with no sphincter reconstructive surgery advanced to permanent SNM implantation ($p = 0.425$). Neither did prior sphincter reconstructive surgery affect the final treatment outcome, with 22 (66.7%) of the patients with a history of sphincter reconstructive surgery and 118 (59.6%) without previous sphincter repair having a successful final treatment outcome ($p = 0.442$). A total of 58 patients had a patent EAS defect and no history of sphincter repair prior to SNM test initiation. When these patients were compared to patients with a history of prior sphincter repair, there was no difference in the test phase ($p = 0.618$) or final treatment outcomes ($p = 0.738$).

Discussion

This is the largest study in a national multicentre setting of the effects of anal sphincter lesions on SNM treatment outcomes published to date. Our study features a relatively large heterogeneous cohort of patients who had undergone EAUS imaging prior to SNM testing.

There were differences in SNM test settings among patients with different types of sphincter lesions. It would appear that a patent IAS defect had an effect on the signal length setting during the test phase. An IAS defect did not have an impact on the permanent SNM settings. Patients with a history of delayed sphincter repair had had more test attempts per patient compared to patients with no history of sphincter repair. The clinical relevance of these findings is unclear.

A patent sphincter defect or a history of previous sphincter reconstructive surgery had no effect on the SNM test or final treatment outcome. This finding supports results from earlier studies that an intact sphincter is not a prerequisite for successful SNM treatment [26, 27]. Results of this study indicate that EAUS findings do not influence the outcome of SNM treatment. Though EAUS is a safe and fast diagnostic tool, the imaging process could cause patients discomfort. Furthermore, the hardware for EAUS imaging is not widely available in Finland. Imaging of the sphincters by EAUS seems to lack diagnostic value when considering SNM treatment outcomes.

Table 3 Sacral neuromodulator settings in each group during the test phase

	Normal sphincters	Pathologic EAS	Pathologic IAS	Pathologic EAS and IAS	Number of patients analysed	*p* value[1]
Test phase settings						
Stimulation amplitude (V)	1.16	1.21	1.03	0.99	112	0.630
Stimulation frequency (Hz)	18.27	17.31	15.32	19.40	103	0.148
Stimulation signal length (ms)	207.31	207.0	223.79	203.68	97	0.002
Permanent modulator settings						
Stimulation amplitude (V)	1.19	1.22	1.25	1.27	114	0.793
Stimulation frequency (Hz)	16.46	14.88	15.55	15.7	109	0.673
Stimulation signal length (ms)	207.17	230.0	221.0	204.44	108	0.099

[1] Kruskal-Wallis test

EAS external anal sphincter, *IAS* internal anal sphincter

Our results indicate no difference in treatment success rates between patients with a patent EAS defect who have been implanted before any attempts at sphincter repair compared to patients with previous sphincter reconstructive surgery. This raises the question of the necessity of sphincter reconstructive surgery prior to SNM treatment. Earlier studies have shown that a sphincter lesion of up to 180 degrees does not have an effect on SNM treatment outcome [28, 29]. A small study has even shown SNM to be superior to sphincteroplasty when comparing postoperative Wexner scores [20]. It can also be argued that the delayed surgical sphincter reconstructive surgery is unnecessary and patients with persistent obstetric sphincter or iatrogenic injury should be considered primarily for SNM treatment. There is evidence for refraining from delayed sphincter reconstructive surgery after obstetric sphincter injury in the elderly population, due to disappointing results [12]. However, it must be emphasised that a successful primary sphincter repair after OASI has the best medium- and long-term results [30]. The success of delayed sphincter reconstructive surgery may depend on the time from the initial injury (i.e. weeks, months or years). Since we had not included the delay from initial injury to sphincter reconstructive surgery in our data collection protocol, further research is needed to answer this question.

This was a retrospective registry study with all the limitations of such studies. The main limitation of this study was the absence of a uniform treatment success evaluation method. This highlights the need for a centralised national database of SNM patients. Further limitations arise from the fact that data on EAUS findings was collected from written imaging reports saved in the patients' files in the digital databases of each hospital.

Conclusion

In this Finnish national cohort of patients, the presence of a patent sphincter defect or a history of delayed sphincter reconstructive surgery did not have any significant effect on the outcome of SNM treatment for FI. The results of this study support the argument of advocating SNM treatment in place of delayed sphincter reconstructive surgery for patients with obstetric or iatrogenic sphincter injuries, regardless of the EAUS findings.

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Compliance with ethical standards

This study was conducted in accordance with Finnish Medical Research Act 488/199, 295/2004 and approved by the Ethics Committee of the Hospital District of Southwest Finland (ETMK: 163/1801/2015).

Appendix 1

The EAUS imaging devices were all supplied by BK Medical. The models varied over the period of 1999–2017, with models Cheetah and Leopard being in use from 1999 to 2002, Falcon from 1999 to 2009, Hawk from 2000 to 2009, Pro Focus Yellow and Green from 2005 to 2010, Pro Focus Blue from 2005 to 2012, Pro Focus Ultraview and Flex Focus 400 from 2009 to 2017, Flex Focus 500 from 2011 to 2017, Flex Focus 800 from 2012 to 2017 and bk3000 and bk5000 from 2014 to 2017. Transducers used with these scanners have varied over the period from 1999 to 2017, with model 1850 being in use from 1999 to 2012, model 2050 from 1999 to 2012, model 2052 from 2005 to 2017 and model 20R3 from 2015 to 2017

Appendix 2

All of the implanted devices were supplied by Medtronic® Inc. (Minneapolis, Minnesota, USA). Until 2002, a non-tined lead was used. Model 3057 PNE (Medtronic® Inc. Minneapolis, USA) was used for temporary evaluation of therapeutic success. A Quadripolar lead model 3093 tined lead was used from 2003 and changed to model 3889 in 2014

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